

CLAIMS:

1. A system for detecting a target biological analyte, the system comprising:
a surface acoustic wave sensor comprising a detection surface;
5 a capture agent located on the detection surface, wherein the capture agent is capable of selectively attaching the target biological analyte to the detection surface;
a detection chamber located within an interior volume of a housing, the detection chamber comprising a volume defined by the detection surface and an opposing surface spaced apart from and facing the detection surface, wherein the
10 opposing surface of the detection chamber comprises a flow front control feature;
a waste chamber located within the interior volume of the housing, the waste chamber in fluid communication with the detection chamber;
means for driving the shear horizontal surface acoustic wave sensor;
means for analyzing data from the surface acoustic wave sensor to determine
15 if target biological analyte is coupled to the capture agent.
2. A system according to claim 1, wherein the surface acoustic wave sensor comprises a shear horizontal surface acoustic wave sensor.
- 20 3. A system according to claim 1, wherein the flow front control feature comprises discrete structures protruding from and separated by a land area on the opposing surface of the detection chamber.
4. A system according to claim 1, wherein the flow front control feature
25 comprises one or more channels in the opposing surface of detection chamber.
5. A system according to claim 1, wherein the flow front control feature comprises one or more regions of hydrophobic material occupying a portion of the opposing surface and one or more regions of hydrophilic material occupying a
30 portion of the opposing surface.
6. A system according to claim 1, further comprising absorbent material located within the waste chamber.

7. A system according to claim 1, wherein the cartridge further comprises capillary structure located between the detection chamber and the waste chamber.
8. A system according to claim 1, further comprising a vent that, when open,
5 places the interior volume of the housing in fluid communication with ambient atmosphere.
9. A system according to claim 8, further comprising a closure element operably attached to the vent.
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10. A system according to claim 1, further comprising a fluid monitor operably connected to the housing, wherein liquid located within the interior volume of the housing can be sensed by the fluid monitor.
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11. A system according to claim 1, further comprising a magnetic field generator capable of providing a magnetic field proximate the detection surface.
12. A system according to claim 1, further comprising a one or more sealed modules, wherein each module of the one or more sealed modules comprises an exit
20 port attached to the housing through one or more module ports that open into the interior volume of the housing, wherein at least one module of the one or more sealed modules contains a liquid isolated from the interior volume of the housing.
13. A system according to claim 12, wherein at least one module of the one or
25 more sealed modules comprises a selected reagent.
14. A system according to claim 12, wherein at least one module of the one or more sealed modules comprises a lysing agent.
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15. A system according to claim 12, wherein at least one module of the one or more sealed modules comprises an input port opening into a chamber within the module.

16. A system according to claim 12, wherein at least one module of the one or more sealed modules comprises:

a first chamber comprising a liquid located therein;

a second chamber comprising a selected reagent located therein; and

5 an inter-chamber seal isolating the second chamber from the first chamber within the at least one module.

17. A system according to claim 12, further comprising means for moving material within at least one module of the one or more sealed modules into the
10 interior volume of the housing.

18. A system according to claim 12, wherein at least one module of the one or more sealed modules further comprises:

an exit seal closing the exit port of the at least one module;

15 a plunger located within the at least one module, wherein the plunger is movable from a loaded position in which the plunger is distal from the exit port to an unloaded position in which the plunger is proximate the exit port;

wherein movement of the plunger towards the exit port opens the exit seal such that material from the at least one module exits through the exit port into
20 the interior volume of the housing.

19. A system according to claim 18, further comprising an actuator operably coupled to the plunger of the at least one module comprising a plunger, wherein the actuator is capable of moving the plunger from the loaded position to the unloaded
25 position.

20. A system according to claim 19, further comprising a fluid monitor operably connected to the housing, wherein liquid located within the interior volume of the housing can be sensed by the fluid monitor.
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21. A system according to claim 20, further comprising a controller operably connected to the actuator and the fluid monitor, wherein the controller is capable of operating the actuator based on a signal from the fluid monitor.

22. A system according to claim 1, further comprising a module attached to the housing, wherein the module comprises:
- a module housing comprising an exit port and a sealed interior volume;
 - an exit seal located over the exit port;
 - 5 a chamber located within the interior volume of the module housing, the chamber comprising one or more reagents located therein;
 - a plunger movable from a loaded position in which the plunger is distal from the exit port to an unloaded position in which the plunger is proximate the exit port; and
 - 10 an input port in fluid communication with the chamber, wherein the input port enters the chamber between the plunger and the exit port when the plunger is in the loaded position;
- wherein movement of the plunger towards the exit port opens the exit seal such that material from the interior volume of the module housing exits through the
- 15 exit port into the interior volume of the housing.
23. A system for detecting a target biological analyte, the system comprising:
- a shear horizontal surface acoustic wave sensor comprising a detection surface;
 - 20 a capture agent located on the detection surface, wherein the capture agent is capable of selectively attaching the target biological analyte to the detection surface;
 - a detection chamber located within an interior volume of a housing, the detection chamber comprising a volume defined by the detection surface and an opposing surface spaced from and facing the detection surface, wherein the
 - 25 opposing surface of the detection chamber comprises a flow control feature;
 - a waste chamber in fluid communication with the detection chamber, wherein absorbent material is located within the waste chamber;
 - capillary structure located between the detection chamber and the waste chamber;
 - 30 at least one module comprising an exit port attached to the housing through a module port that opens into the interior volume of the housing, wherein the at least one module contains a selected reagent within a chamber, and further wherein the at least one module comprises an exit seal closing the exit port of the at least one

module, a plunger located within the at least one module, wherein the plunger is movable from a loaded position in which the plunger is distal from the exit port to an unloaded position in which the plunger is proximate the exit port, wherein movement of the plunger towards the exit port opens the exit seal and delivers
5 material from the chamber of the at least one module into the interior volume of the housing through the exit port;

an actuator operably coupled to the plunger of the at least one module, wherein the actuator is capable of moving the plunger from the loaded position to the unloaded position;

10 means for driving the shear horizontal surface acoustic wave sensor; and
means for analyzing data from the shear horizontal surface acoustic wave sensor to determine if the target biological analyte is coupled to the capture agent.

24. A system according to claim 23, further comprising a fluid monitor operably
15 connected to the housing, wherein liquid located within the interior volume of the housing can be sensed by the fluid monitor.

25. A system according to claim 23, further comprising a controller operably connected to the actuator and the fluid monitor, wherein the controller is capable of
20 operating the actuator based on a signal from the fluid monitor.

26. A system according to claim 23, wherein the at least one module comprises a input port opening into the chamber within the at least one module.

25 27. A system according to claim 23, wherein the at least one module comprises:
a first chamber comprising a liquid located therein;
a second chamber comprising the selected reagent; and
an inter-chamber seal isolating the second chamber from the first chamber
within the at least one module.

30 28. A system according to claim 23, further comprising a magnetic field generator capable of providing a magnetic field proximate the detection surface, and

wherein the at least one module comprises magnetic particles located in the chamber.

29. A method of detecting a target biological analyte using the system of claim 5 1, the method comprising:
- providing a system according to claim 1;
 - contacting sample material with a mass modification agent, wherein a target biological analyte within the sample material interacts with the mass-modification agent such that a mass-modified target biological analyte is obtained within the test 10 sample;
 - contacting the detection surface of the surface acoustic wave device with the mass-modified test sample by delivering the test sample to the detection chamber;
 - selectively attaching the mass-modified target biological analyte to the detection surface; and
 - 15 operating the surface acoustic wave device to detect the attached mass-modified biological analyte while the detection surface is submersed in liquid.

30. A method according to claim 29, wherein the surface acoustic wave device comprises a shear horizontal surface acoustic wave device.

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31. A method according to claim 29, wherein the system comprises a vent that, when open, places the interior volume of the housing in fluid communication with ambient atmosphere, and wherein the method further comprises controlling flow of the sample material through the detection chamber by adjusting a vent opening size 25 of the vent.

32. A method according to claim 29, wherein the system comprises one or more modules, wherein each module of the one or more modules comprises an exit port attached to the housing through a module port that opens into the interior volume of 30 the housing, wherein at least one module of the one or more modules contains the mass-modification agent within a chamber, and further wherein each module of the one or more modules comprises an exit seal closing the exit port of the at least one module and a plunger located within the module, wherein the plunger is movable

from a loaded position in which the plunger is distal from the exit port to an unloaded position in which the plunger is proximate the exit port;

wherein the method further comprises moving the plunger towards the exit port to open the exit seal and deliver material from the chamber of at least one
5 module of the one or more modules into the interior volume of the housing through the exit port.

33. A method according to claim 32, wherein at least one module comprises a sealed module comprising liquid isolated from the interior volume of the housing;
10 wherein the method further comprises moving the plunger towards the exit port to open the exit seal and deliver the liquid into the interior volume of the housing through the exit port.

34. A method according to claim 32, wherein at least one module of the one or
15 more modules comprises magnetic particles in the chamber.

35. A system according to claim 32, wherein the mass-modification agent comprises a chemical fractionating agent.

20 36. A method according to claim 32, wherein at least one module of the one or more modules comprises an input port opening into the chamber within the module;
wherein the method comprises delivering a test specimen into the chamber of the at least one module through the input port;
and wherein the method comprises moving the plunger of the at least one
25 module towards the exit port to open the exit seal and deliver the test specimen from the chamber of the at least one module into the interior volume of the housing through the exit port.

37. A method according to claim 32, wherein at least one module of the one or
30 more modules comprises a first chamber comprising a liquid located therein,
a second chamber comprising a selected reagent located therein, and an inter-chamber seal isolating the second chamber from the first chamber within the at least one module;

wherein the method comprises moving the plunger of the at least one module towards the exit port to open the inter chamber seal, wherein the liquid in the first chamber contacts the selected reagent in the second chamber;

5 and wherein the method further comprises moving the plunger of the at least one module towards the exit port to open the exit seal and deliver material the liquid and the selected reagent into the interior volume of the housing through the exit port.

38. A method according to claim 32, wherein at least one module of the one or more modules comprises magnetic particles located therein;

10 and wherein the method further comprises:

attaching the magnetic particles in the at least one module to the target biological analyte; and

attracting the magnetic particles towards the detection surface using a magnetic field proximate the detection surface.

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39. A method according to claim 32, wherein the system further comprises an actuator operably coupled to the plunger of at least one module of the one or more modules, wherein the actuator is capable of moving the plunger from the loaded position to the unloaded position;

20 and wherein the system further comprises a fluid monitor operably connected to the interior volume of the housing, wherein liquid located within the interior volume of the housing can be sensed by the fluid monitor;

and wherein the method further comprises operating the actuator to deliver material into the interior chamber of the housing in response to a signal from the
25 fluid monitor.

40. A method of detecting a biological analyte, the method comprising:
fractionating target biological analyte located within sample material;
contacting a detection surface of a shear horizontal surface acoustic wave
30 sensor with the sample material containing the fractionated target biological analyte;
selectively attaching the fractionated target biological analyte to the detection surface; and

operating the shear horizontal surface acoustic wave sensor to detect the attached fractionated target biological analyte while the detection surface is submersed in liquid.

5 41. A method according to claim 40, wherein the fractionating comprises chemically fractionating the target biological analyte in the sample material.

42. A method according to claim 40, wherein the fractionating comprises mechanically fractionating the target biological analyte in the sample material.

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43. A method according to claim 40, wherein the fractionating comprises thermally fractionating the target biological analyte in the sample material.

15 44. A method according to claim 40, wherein the fractionating comprises electrically fractionating the target biological analyte in the sample material.

45. A method according to claim 40, wherein the shear horizontal surface acoustic wave sensor comprises a Love Wave shear horizontal surface acoustic wave sensor.

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46. A shear horizontal surface acoustic wave sensor comprising:
a piezoelectric substrate comprising a major surface;
at least one transducer on the major surface of the piezoelectric substrate,
wherein the at least one transducer defines an acoustic path on the major surface of
25 the piezoelectric substrate, wherein the acoustic path comprises a first end and a second end;

wherein the at least one transducer comprises a contact pad on the major surface of the piezoelectric substrate, wherein the contact pad is located off to a first side of the acoustic path and between the first end and the second end of the acoustic path, wherein the contact pad is connected to the at least one transducer by a lead.
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47. A sensor according to claim 46, wherein the at least one transducer comprises a pair of contact pads on the major surface of the piezoelectric substrate,

wherein the pair of contact pads are located off to the first side of the acoustic path and between the first end and the second end of the acoustic path, wherein the contact pads are each connected to the at least one transducer by a lead.